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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,799	09/21/2004	Jack T Johansen	056258-5075	3924

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MORGAN LEWIS & BOCKIUS LLP  
1111 PENNSYLVANIA AVENUE NW  
WASHINGTON, DC 20004

EXAMINER
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STAPLES, MARK

ART UNIT	PAPER NUMBER
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1637

MAIL DATE	DELIVERY MODE
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12/27/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/508,799

Applicant(s)

JOHANSEN, JACK T

Examiner

Mark Staples

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicant's amendment of claims 1, 4, 5, and 27 in the paper filed on 10/04/2007 is acknowledged.

Claims 1-27 are pending and at issue.

Applicant's arguments filed on 10/04/2007 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### **Rejections that are Withdrawn**

##### ***Claim Rejections Withdrawn - 35 USC § 112 Second Paragraph***

2. The rejections of claims 1-27 under 35 USC § 112 Second Paragraph are withdrawn in light of Applicant's amendments to these claims which overcome these rejections.

**Rejections that are Maintained**

***Claim Rejections Maintained - 35 USC § 102***

3. The rejection of claims 1-8, 10, 12, 14, 16, 18, 19, 24, and 25 under 35 U.S.C. 102(b) as being anticipated by Bambara et al. (1975) is maintained. Applicant's arguments filed 10/04/2007 have been fully considered but they are not persuasive.

Applicant argues on page 5 and 6 that since Bambara et al. in a first example teach the additional prior step of loading the sample onto a DEAE-cellulose column before performing the steps of the claimed method that Bambara et al. do not anticipate the claimed method (1st full paragraph in the 2<sup>nd</sup> column on p. 4608). However, claim 1 recites a method "comprising the steps". The MPEP in Section 2111.03 [R-3]

*Transitional Phrases* states:

"The transitional term 'comprising', which is synonymous with 'including,' 'containing,' or 'characterized by,' is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ('like the term comprising,' the terms containing' and mixture' are open-ended.').< Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ('The transition comprising' in a method claim indicates that the claim is open-ended and allows for additional steps major amounts") . . . . "

Thus the claim language allows for additional steps. Thus this argument is not persuasive.

Applicant also argues the pH of the prior step of Bambara et al. is the same pH as the elution step, where in the claimed method the elution step should be a higher pH. However after loading the sample, Bambara et al. lower the pH and then in order to elute the sample change the pH to higher pH. Bambara et al. thus teach the claimed invention. Furthermore, the binding of the target oligonucleotide at the lower pH and its elution at a higher pH are properties of the target oligonucleotide. The method of Bambara et al. and the claimed invention rely on these same intrinsic properties of the target oligonucleotide. The teachings of Bambara et al. anticipate the claimed invention.

Applicant then argues on p. 6 that in a second example Bambara et al. first separate the primer oligonucleotide from failed primers (1st full paragraph in the 2<sup>nd</sup> column on p. 4608). This is actually the same example as the first example noted above, Applicant appears to be arguing a different aspect of that example. Regardless, the response to Applicant's argument is the same as above. That is, that additional steps are not precluded from claim 1. Furthermore, Bambara et al. fully teach the separation of the impurity of urea from the target oligonucleotide which fully reads on the claimed invention, and as cited in more detail in the prior Office Action.

Thus Applicant's arguments are not persuasive and the rejection is maintained.

***Claim Rejections Maintained - 35 USC § 103***

4. The rejection of claims 13 and 17 under 35 U.S.C. 103(a) as being unpatentable over Bambara et al. (1975) as applied to claims 1 and 6 above, and further in view of Lu et al. (1994) is maintained. Applicant's argument is not persuasive. Applicant argues that since the rejection of claims as anticipated by Bambara et al. should be withdrawn, so should this rejection be withdrawn. However the rejection of claims as anticipated by Bambara et al. is maintained. Thus this rejection is maintained.

5. The rejection of claims 4, 8, and 15 under 35 U.S.C. 103(a) as being unpatentable over Bambara et al. (1975) as applied to claims 1 and 7 above, and further in view of Asteriadis et al. (1976) is maintained. Applicant's argument is not persuasive. Applicant argues that since the rejection of claims as anticipated by Bambara et al. should be withdrawn, so should this rejection be withdrawn. However the rejection of claims as anticipated by Bambara et al. is maintained. Thus this rejection is maintained.

6. The rejection of claims 8 and 11 under 35 U.S.C. 103(a) as being unpatentable over Bambara et al. (1975) as applied to claims 1 and 10 above, and further in view of Jin-Yan et al. (WO9527718 published in 1995) is maintained. Applicant's argument is not persuasive. Applicant argues that since the rejection of claims as anticipated by Bambara et al. should be withdrawn, so should this rejection be withdrawn. However the rejection of claims as anticipated by Bambara et al. is maintained. Thus this rejection is maintained.

7. The rejection of claims 9 under 35 U.S.C. 103(a) as being unpatentable over Bambara et al. (1975) as applied to claims 1 and 8 above, and further in view of Crane et al. (US Patent 5,092,992 issued 1992) is maintained. Applicant's argument is not persuasive. Applicant argues that since the rejection of claims as anticipated by Bambara et al. should be withdrawn, so should this rejection be withdrawn. However the rejection of claims as anticipated by Bambara et al. is maintained. Thus this rejection is maintained.

8. The rejection of claims 20-23 and 26 under 35 U.S.C. 103(a) as being unpatentable over Bambara et al. (1975) as applied to claims 1 above and further in view of Fruchtel et al. (1996) is maintained. Applicant's argument is not persuasive. Applicant argues that since the rejection of claims as anticipated by Bambara et al. should be withdrawn, so should this rejection be withdrawn. However the rejection of claims as anticipated by Bambara et al. is maintained. Thus this rejection is maintained.

9. The rejection of claims 27 is 35 U.S.C. 103(a) as being unpatentable over Bambara et al. (1975) as applied to claim 1 above and further in view of Crane et al. (1992) and Asteriadis et al. (1976) is maintained. Applicant's argument is not persuasive. Applicant argues that since the rejection of claims as anticipated by Bambara et al. should be withdrawn, so should this rejection be withdrawn. However the rejection of claims as anticipated by Bambara et al. is maintained. Thus this rejection is maintained.

In summary, all prior art rejections are maintained.

**Conclusion**

10. No claim is free of the prior art.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples *MS*  
Examiner  
Art Unit 1637  
December 19, 2007

*Kenneth R. Horlick*  
KENNETH R. HORLICK, PH.D.  
PRIMARY EXAMINER  
12/20/07